



Approved for use through 07/31/2008. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				Complete if Known	
				Application Number	10/615,213-Conf. #8060
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Filing Date	July 7, 2003
				First Named Inventor	William E. Bay
				Art Unit	1625
				Examiner Name	R. J. Desai
Sheet	1	of	4	Attorney Docket Number	01946/100G906-US2

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (# known)			
RO	AA	3,795,739	3/5/74	Birkmayer et al.	
RO	AB	3,939,253	2/17/76	Bodor et al.	
RO	AC	4,035,507	7/12/77	Bodor et al.	
RO	AD	4,061,466	12/6/77	Sjoholm et al.	
RO	AE	4,147,767	4/3/79	Yapel	
RO	AF	4,207,341	6/10/80	Mandfred et al.	
RO	AG	4,221,815	9/9/80	Weyer et al.	
RO	AH	4,238,506	12/9/80	Stach, deceased et al.	
RO	AI	4,239,754	12/16/80	Sache et al.	
RO	AJ	4,393,192	7/12/83	Curatolo et al.	
RO	AK	4,442,090	4/10/84	Takeya et al.	
RO	AL	4,499,299	2/12/85	Bernstein et al.	
RO	AM	4,462,991	7/31/84	Higuchi et al.	
RO	AN	4,656,161	4/7/87	Herr et al.	
RO	AO	4,654,327	3/31/87	Teng	
RO	AP	4,692,433	8/8/87	Hosteller et al.	
RO	AQ	4,757,066	7/12/88	Shiokari et al.	
RO	AR	4,835,312	5/30/89	Itoh et al.	
RO	AS	4,873,087	10/10/89	Morishita et al.	
RO	AT	4,878,942	11/7/89	Motegi et al.	
RO	AU	4,900,730	2/13/90	Miyauchi	
RO	AV	4,927,928	5/22/90	Shroot et al.	
RO	AW	5,066,487	11/19/91	Morelle et al.	
RO	AX	5,352,461	10/4/94	Feldstein et al.	
RO	AY	5,665,700	9/9/97	Cho et al.	
RO	AZ	5,705,529	1/6/98	Matyus et al.	
RO	BA	5,447,728	9/5/95	Milstein et al.	
RO	BB	5,451,410	9/19/95	Milstein et al.	
RO	BC	5,541,155	7/30/96	Leone-Bay et al.	
RO	BD	5,629,020	5/13/97	Leone-Bay et al.	
RO	BE	5,643,957	7/1/97	Leone-Bay et al.	
RO	BF	5,650,386	7/22/97	Leone-Bay et al.	
RO	BG	5,709,861	1/20/98	Santiago et al.	
RO	BH	5,714,167	2/3/98	Milstein et al.	
RO	BI	5,750,147	5/12/98	Kantor et al.	
RO	BJ	5,766,633	6/16/98	Milstein et al.	
RO	BK	5,773,647	6/30/98	Leone-Bay et al.	
RO	BL	5,776,888	7/07/98	Leone-Bay et al.	
RO	BM	RE35862	7/28/98	Steiner et al.	
RO	BN	5,792,451	8/11/98	Sarubbi et al.	
RO	BO	5,804,688	9/8/98	Leone-Bay et al.	

Examiner Signature	R. Desai	Date Considered	3/9/06
--------------------	----------	-----------------	--------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete If Known	
				Application Number	10/615,213-Conf. #8060
				Filing Date	July 7, 2003
				First Named Inventor	William E. Bay
				Art Unit	1625
				Examiner Name	R. J. Desai
				Attorney Docket Number	01946/100G906-US2
Sheet	2	of	4		

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)				
RD	BP	5,811,127		9/22/98	Milstein et al.	
RD	BQ	5,863,944		1/26/99	Leone-Bay et al.	
RD	BR	5,866,536		2/2/99	Leone-Bay et al.	
RD	BS	5,876,710		3/2/99	Leone-Bay et al.	
RD	BT	5,879,681		3/9/99	Leone-Bay et al.	
RD	BU	5,939,381		8/17/99	Leone-Bay et al.	
RD	BV	5,958,457		9/28/99	Santiago et al.	
RD	BW	5,965,121		10/12/99	Leone-Bay et al.	
RD	BX	5,989,539		11/23/99	Leone-Bay et al.	
RD	BY	5,990,166		11/23/99	Leone-Bay et al.	
RD	BZ	6,001,347		12/14/99	Leone-Bay et al.	
RD	CA	6,051,258		4/18/00	Kantor	
RD	CB	6,051,561		4/18/00	Leone-Bay et al.	
RD	CC	6,060,513		5/9/00	Leone-Bay et al.	
RD	CD	6,071,510		6/6/00	Leone-Bay et al.	
RD	CE	6,071,538		6/6/00	Milstein et al.	
RD	CF	6,090,958		7/18/00	Leone-Ba et al.	
RD	CG	6,099,856		8/8/00	Milstein et al.	
RD	CH	6,221,367		4/24/01	Milstein et al.	
RD	CI	6,242,495		6/5/01	Leone-Bay et al.	
RD	CJ	6,245,359		6/12/01	Milstein et al.	
RD	CK	6,313,088		11/6/01	Leone-Bay et al.	
RD	CL	6,344,213		2/5/02	Leone-Bay et al.	
RD	CM	6,346,242		2/12/02	Leone-Bay et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
RD		EP-0036145	9/23/81			
RD		GB-2095994	10/13/82			
RD		EP-226223	6/27/87			
RD		EP-0365183	10/6/89			
RD		WO-8807378	10/6/98			
RD		EP-0576941	6/19/93			
RD		JP-2239980	9/21/90			
RD		EP-0517211	9/12/92			
RD		WO-9747470	12/18/97			
RD		WO-0007979	5/18/00			
RD		WO-0006534	2/10/00			
RD		WO-0006184	2/10/00			

Examiner Signature	<i>R. Desai</i>	Date Considered	3/9/06
--------------------	-----------------	-----------------	--------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/615,213-Conf. #8060
				Filing Date	July 7, 2003
				First Named Inventor	William E. Bay
				Art Unit	1625
				Examiner Name	R. J. Desai
Sheet	3	of	4	Attorney Docket Number	01946/100G906-US2

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³	Number ⁴ +Kind Code ⁵ (if known)			
RJ		WO	0048589	8/24/00		
RJ		WO	0009390	10/12/00		
RJ		ES	369853	7/16/71		
RJ		WO	9929685	6/17/99		
RJ		EP	0225189	10/6/87		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
R		Picciola G.: "Sintesi Di Acidi Chiazolinici E. Benzossazonici E Studio Delle Loro Proprieta Antiniammatore" IT, Societa Chimica Italiana Pavia vol 31, no. 9 pgs 655-664 and English Translation	
R		Chem Abs 73548-12-6 (4/1991)	
RP		Chem Abs 70204-54-5 (4/1991)	
RP		Chem Abs 184360-83-342 (1975) "Solubility and disassociation constants of some alicyclic acids"	
RP		Chemical Abstract, Vol. 99(23) Abst. No. 191473h (1983)	
RP		Riveria, Theresa M. et al. "Oral Delivery of Heparin in Combination with Sodium N-[8-2-hydroxybenzoyl]amino]caprylate: Pharmacological Considerations" Pharmaceutical Research vol 14(12) 1830-1834 (1979)	
RP		Leone-Bay, A. et al., "The evolution of an oral heparin dosing solution" Drugs of the Future vol 22 (8) 885-891 (1997)	
R		Brayden, D. et al. "Heparin Absorption across the intestine; Effects of Sodium N-[8-2-hydroxybenzoyl]Amino] Caprylate in rat in situ intestinal instillations and in Caco-2 monolayers" Pharmaceutical Research vol 14(12) 1772-1779 (1997)	
R		Leone-Bay, A. "Acylated non-alpha-amino acids as novel agents for the oral delivery of heparin sodium, USP" Journal of Controlled Release 50: 41-49 (1998)	
RP		Leone-Bay, A. "4-[4-(2-Hydroxybenzoyl) amino]phenyl]-butyric Acids as Novel Oral Delivery Agent for Recombinant Human Growth Hormone"; Journal of Medicinal Chemistry vol. 39, no 13 pp 2571-2578 (1996)	
RP		Leone-Bay, A. "N-Acetylated alpha-amino acids as novel oral delivery agents for proteins" ;Journal of Medicinal Chemistry vol 38, 4263-4269 (1995)	
R		Leone-Bay, A. "N-Acetylated alpha-amino acids as novel oral delivery agents for proteins" ;Journal of Medicinal Chemistry vol 38, 4257-4262 (1995)	

Examiner Signature	<i>RJ Desai</i>	Date Considered	3/9/06
-----------------------	-----------------	--------------------	--------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/615,213-Conf. #8060
				Filing Date	July 7, 2003
				First Named Inventor	William E. Bay
				Art Unit	1625
				Examiner Name	R. J. Desai
Sheet	4	of	4	Attorney Docket Number	01946/100G906-US2

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
RJ		Ho Koc-Kan; et al. "A Practical Synthesis of ω -aminoalkanoic acid derivatives from Cycloalkanones" Synthetic Communication, vol. 26, no. 14:2641-2649 (1996)	
RJ		Gurrier and Siracusa: "Thermal Condensation of Some alpha-aminoacids with Phthalic Acid" Thermochimica Acta, 7 (1973) 231-239	
RJ		Amino Yusuke et al. Chem Pharm Bull 36 pgs 4426-4434 (1998)	
RJ		Brown et al., . Med. Chem. 27:79-81 (1984)	
RJ		Johansen, Marianne, et al. "The Kinetics of decompn. Of various N-Mannichi bases of salicylamide" Int. J. Pharm. 1980, 7(2): 119-27 (1980)	
RJ		August 1, 2000 International Search Report issued in connection with PCT Application No. PCT/US00/09390	
RJ		Baughman, R. et al., Circulation (1998), 98 (16) 1610-1615.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	<i>RJ Desai</i>	Date Considered	3/9/06
-----------------------	-----------------	--------------------	--------